

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: William BAXENDALE, *et al.*
Serial No: 10/527,767
Filing Date: September 12, 2005
Title: Chicken Astrovirus Type 2
Confirmation No: 5168
Group Art Unit: 1648
Examiner: Hurt, Sharon L.
Attorney Ref: 2002.016 US

April 29, 2009
APPEAL BRIEF

Mail Stop Appeal
Board of Patent Appeals
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir/Madam:

Pursuant to Appellants' February 5, 2009, Notice of Appeal, Appellants appeal all the claim rejections in the August 6, 2008, final Office action directed to the above-referenced patent application. In support of this appeal, Appellants provide the following information, argument, and fee in accordance with 37 C.F.R. §41.37 and MPEP §§1205 and 1205.02.

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I. REAL PARTY IN INTEREST (37 C.F.R. §41.37(c)(1)(i))

The real party in interest in this appeal is Intervet International B.V. This ownership is evidenced by assignment documents recorded at Reel 016767, Frame 0270 (recorded on September 9, 2005), and Reel 018490, Frame 0365 (recorded on November 8, 2006).

II. RELATED APPEALS AND INTERFERENCES (37 C.F.R. §41.37(c)(1)(ii))

Appellants are not aware of any prior or pending appeals, judicial proceedings, or interferences that may be related to, directly affect, or be directly affected by or have bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS (37 C.F.R. §41.37(c)(1)(iii))

A total of 10 claims have been introduced in this patent application. Claims 2 and 3 have been canceled and claims 1 and 4-10 remain pending. All pending claims have been rejected. This appeal requests reversal of all the rejections.

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IV. STATUS OF AMENDMENTS (37 C.F.R. §41.37(c)(1)(iv))

Appellants filed an amendment on December 8, 2008, in response to the final Office action. The amendments were entered for the purpose of appeal in an Advisory Action dated February 3, 2009. These amended claims are now on appeal.

V. SUMMARY OF CLAIMED SUBJECT MATTER (37 C.F.R. §41.37(c)(1)(v))

The present invention results from Appellants' discovery of a novel subtype of avian astrovirus isolated from chickens. The novel subtype of avian astrovirus has been shown by them to be immunologically distinct from known chicken astroviruses and from other avian astroviruses. There is one independent claim directed to the chicken astrovirus type 2 (CAstV-2). There are also dependent claims directed to immunogenic compositions comprising the CAstV-2, a method for the preparation for CAstV-2 antigen, a method for the preparation of the immunogenic composition and a method for raising an immune response in poultry, summarized as follows:

- A. **Claim 1** is directed to the novel chicken astrovirus type 2 (CAstV-2), characterized by being the deposited specimen under accession number I-2932 at the CNCM of the Institute Pasteur, Paris, France or a CAstV-2 able to induce antiserum having antibody titers greater than or equal to 128 against the deposited virus as measured in a virus neutralization assay, and a titer greater than or equal to 32 as measured in an immunofluorescence assay. See, e.g., Appellants' specification page 10 and page 11 for the virus neutralization assay and the immunofluorescence test, respectively. See also Table 1a on page 12 and Table 2 on page 14.
- B. **Claim 4** (as well as 5-7) is directed to immunogenic compositions comprising a CAstV-2 as defined in claim 1, together with a pharmaceutically acceptable carrier or diluent. Claim 9 recites a method for preparing immunogenic compositions. Preparation of immunogenic compositions is described in Example 2, beginning on page 9 of the specification, as well as on page 3, paragraph 1 and paragraph 2.
- C. **Claim 8** is directed to a method for preparing CAstV-2 antigen. Antigen may

be isolated from any virus prepared as in Example 1, beginning on page 8 of the specification.

- D. **Claim 10** is directed to a method for raising an immune response in poultry. Immunization of chickens is described in Example 2, on page 9 of the specification.

**VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL (37 C.F.R.
§41.37(c)(1)(vi))**

Claims 1 and 4-10 have been rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement.

VII. ARGUMENT (37 C.F.R. §41.37(c)(1)(vii))

A. Rejection of claims 1 and 4-10 under 35 U.S.C. §112, first paragraph

Claims 1 and 4-10 have been rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. “The claim language reads on a genus of viruses that can produce antibodies to neutralize the deposited virus. One of skill in the art would not recognize from the specification that the applicant was in possession of the claimed invention. The specification does have support for ‘A chicken astrovirus type 2 (CAstV-2), characterized in that the virus is the CAstV deposited under accession no. I-2932 at the Collection Nationale de Cultures de Microorganismes (CNCM) of the Institute Pasteur, Paris, France.’”

Appellants submit that the written description requirement has been met and this rejection should be withdrawn. Appellants have identified three different specimens of their novel chick astrovirus type 2 subtype and have distinguished them from the known chicken astrovirus ANV (CAst-V-1) and from other avian astroviruses (TastV and DVH-2) in virus neutralization and immunofluorescence assays. Specific limitations on antibody titers required to define a chicken astrovirus as being within the subtype discovered have been included in the claims as limitations on virus neutralization assay (greater than or equal to 128) and immunofluorescence assay (greater than or equal to 32) measurements, which are supported by the experimental results presented in Example 2. Accordingly, Appellants submit that the written description requirement has been met, that they have characterized a novel subtype of chicken astrovirus, and that this objection should be withdrawn. One of skill in the art will recognize by these defining characteristics whether or not an astrovirus is within the subtype claimed and that Appellants had possession of the invention.

Appellants have, in fact, identified a new chicken astrovirus subtype, which they have identified as chicken astrovirus type 2, for short, CAstV-2. The defining example of this virus has been deposited under accession number I-2932 at the CNCM, as recited in the claims. In addition to the deposited virus, Appellants have also demonstrated that they had isolated two other isolates of the same chicken astrovirus type 2, which were identified using the same criteria that are included in claim 1 as characterizing limitations. In demonstrating that the other two isolates are of the same type, Appellants showed, in the results presented in Table 2

on page 14 of the specification, that the other viruses of this subtype meet minimum levels of cross neutralization antibody titer and immunofluorescence. In Example 2, beginning on page 9 of the specification, Appellants provided a written description defining the immunological characterization of their novel chicken astrovirus type 2, including a detailed description of the virus neutralization assay used, as well the immunofluorescence test (pages 10 and 11).

To demonstrate the unique characteristics of the chicken astrovirus type 2 compared with other avian astroviruses, Appellants provided in Tables 1a and 1b, on pages 12 and 13 of the specification, neutralization and immunofluorescence results. These results compared CAstV-2 AS2 with CAstV-1 ANV and turkey astrovirus TstV (Table 1a), and CAstV-2 AS1 with CAstV-1 ANV and duck astrovirus DVH-2 (Table 1b). Then, in Table 2, on page 14, the high levels of cross-reactivity for neutralization and immunofluorescence among CAstV-2 isolates AS1, AS2 and AS3 are reported, which were compared with the negligible cross-reactivity results reported for the non type 2 astrovirus isolates in Tables 1a and 1b.

Appellants have provided a deposited example of their new chicken astrovirus type 2, they have illustrated that other isolates of the same virus subtype have been found and characterized, and they have provided a complete written description of the methods used for measuring neutralization and immunofluorescence, by which they define their novel subtype and by which any skilled practitioner can determine whether or not any example of a chicken astrovirus is within the definition of Appellants' new chicken astrovirus type 2.

The Examiner concluded that Appellants' arguments are not persuasive because the claim, even with the specific minimum requirements for neutralization and immunofluorescence, would read on any virus that can induce cross-reactive antibodies to neutralize the deposited strain. In fact, Appellants have identified a new type of chicken astrovirus that is defined by comparative neutralization and immunofluorescence assays with the deposited virus, requiring specific minimum numerical values for each, and have produced three separate isolates of the novel subtype. Appellants have provided a written description and a process for making and using their novel type 2 astrovirus, in such full, clear, concise and exact terms as to enable any person skilled in the art for which it pertains to make and use the same, as well as setting forth the best mode. Using the methods and information provided, one of ordinary skill can determine if any chicken astrovirus is within

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the CAstV-2 subtype claimed. Appellants' defining criteria, as well as the three isolates obtained, clearly reasonably convey to an artisan that they were in possession of the invention as claimed. [MPEP 2163.02]. That is all that is required under the statute and those requirements have been met.

VIII. DESCRIPTION OF CLAIMS APPENDIX (37 C.F.R. §41.37(c)(1)(viii))

An appendix containing a copy of all the claims involved in the appeal is provided on pages 17-18.

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IX. DESCRIPTION OF EVIDENCE APPENDIX (37 C.F.R. 41.37©(1)(ix))

None.

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X. DESCRIPTION OF RELATED PROCEEDINGS APPENDIX (37 C.F.R.

§41.37(c)(1)(x)

None.

XI. Fee payment and extension request

Appellants authorizes the Commissioner to charge Deposit Account No. **02-2334** for the \$540.00 fee under 37 CFR §41.20(b)(2) for filing this appeal. Appellants also requests a one-month extension to file this brief, and authorizes the Commissioner to charge Deposit Account No. **02-2334** for the corresponding extension fee under 37 CFR §1.17(a)(5). Appellants do not believe that any other fee is due in connection with this filing. If, however, Appellants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. **02-2334**. In addition, if there is ever any other fee deficiency or overpayment in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or credit such overpayment to Deposit Account No. **02-2334**.

* * * * *

Appellants submit that the pending claims are in condition for allowance and request the rejections in the August 6, 2008, final Office action be reversed, and claims 1 and 4-10 be allowed.

Respectfully submitted,

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APPENDIX A
Claims Appendix (37 C.F.R. §41.37(c)(1)(viii))

1. A chicken astrovirus type 2 (CAstV-2), characterised in that the virus is the CAstV deposited under accession no. I-2932 at the Collection Nationale de Cultures de Microorganismes (CNCM) of the Institute Pasteur, Paris, France or a CAstV-2 that is able to induce antiserum having a neutralizing antibody titre greater than or equal to 128 against the deposited virus as measured in a virus neutralization assay and greater than or equal to 32 as measured in an immunofluorescence assay.

Claims 2 – 3 (Canceled)

4. An immunogenic composition comprising a CAstV-2 according to claim 1, together with a pharmaceutically acceptable carrier or diluent.
5. The immunogenic composition according to claim 4, characterized in the CAstV-2 is in a live attenuated form.
6. The immunogenic composition of claim 4, further comprising one or more vaccine components of other pathogens infectious to poultry.
7. The immunogenic composition according to claim 4, further comprising an adjuvant.

8. A method for the preparation of CAstV-2 antigen material, wherein a CAstV-2 according to claim 1 is propagated in a cell culture and subsequently harvested from the cell culture.
9. A method for the preparation of a vaccine according to claim 4, an immunogenic composition, wherein a CAstV-2 according to claim 1 is mixed with a pharmaceutical pharmaceutically acceptable carrier or a diluent.
10. A method for raising an immune response in poultry, against avian astrovirus, comprising administering an immunogenic composition according to claim 4 to poultry.

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APPENDIX B

Evidence Appendix (37 C.F.R. §41.37(c)(1)(ix))

None.

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APPENDIX C
Related Proceedings Appendix (37 C.F.R. §41.37(c)(1)(x))

None.